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DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food & Drug Administration
1141 Central Parkway
Cincinnati, OH 45202

January 9, 1998

WARNING LETTER
CIN-WL-97-607

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Gary Shawkey, President
Incredible Products, Inc.
2717 South Arlington Road, Suite H
Akron, OH 44312-1259

Dear Mr. Shawkey:

This letter is in reference to your firm's marketing and distribution of the products Herbal Energy Boost Capsules and Colloidal Minerals with Vitamins with Aloe Liquid. Claims made in the labeling for these products cause them to be drugs [Section 201(g) of the Federal Food, Drug and Cosmetic Act (the Act)].

Herbal Energy Boost contains the ingredient saw palmetto, and the descriptive brochure claims that "studies confirm an effect on male sex hormones" and "an extract has exhibited positive clinical results in treating enlargement of the prostate."

Additional therapeutic claims appear in the labeling of the descriptive brochure which lists the ingredients in Herbal Energy Boost. The noted claims include the following examples:

- Bladderwrack - helps normalize the thyroid gland and aids in combating obesity.
- Boron - may be necessary to help prevent bone loss, osteoporosis and helps prevent arthritis
- Chromium Picolinate - Chromium deficiencies can cause difficulties in the regulation of blood sugar. Supplementation of 200 mcg daily can benefit some type II (adult onset) diabetics and people suffering from hypoglycemia. Chromium's effects on blood sugar can also spill over to affect fat metabolism and blood cholesterol levels. It thus may help prevent heart disease
- Fo-Ti - It is also used to treat dizziness, infertility, anemia and constipation. There is evidence that it lowers blood cholesterol levels, and it is currently being studied for its ability to prevent heart disease and cancer
- Ginkgo - it may help prevent dizziness, hearing loss, tinnitus, stroke and depression. It has potential use in the treatment of impotence, varicose veins, and Alzheimer disease.

- Hawthorne Berries - It can reduce blood pressure and preventpalpitations, arhythmias and arteriosclerosis. May be useful against arthritis.

In addition, the labeling for your product, Colloidal Minerals with Vitamins and Aloe Liquid makes therapeutic claims such as "Aloe is believed to be of benefit in cases of rheumatic fever, acid indigestion, and ulcer. As well as it may help those suffering from inflammatory conditions of the digestive system and other internal organs."

Therapeutic claims are also made for Vitamin E and Vitamin C, which are ingredients in the Colloidal Minerals. The claims for Vitamin E include health conditions associated with the acceleration of the aging process include: cancer, heart disease, Alzheimer's disease, arthritis (and others). For example, claims for Vitamin C include a 43% reduction in mortality rates from cardiovascular disease for those who supplemented with vitamin C. The product also claims that it reduces the cancer death rate by 38% and that diabetes and other diseases were reduced by 20%.

The "Colloidal Minerals with Vitamins and Aloe Liquid" and Herbal Energy Boost capsules are "new drugs" without approved new drug applications.

Further, Benign Prostate Hypertrophy drug products for over the counter human use are subject to a monograph which appears in 21 CFR Part 310. The Food and Drug Administration has determined that there are no effective OTC products that are generally recognized as safe and effective for relief of an enlarged prostate gland. The effective date of this rule is August 27, 1990. Thus, any such product is a new drug (as described in Section 201(p) of the Act).

"New drugs" [Section 201(p)] of the Federal Food, Drug and Cosmetic Act (the Act) may not be legally marketed in the United States without approved New Drug Applications (Section 505 of the Act).

These drugs are also misbranded (Section 502(f)(1) of the Act) because the labeling fails to bear adequate directions for use. The labeling is false and misleading because it suggests that the products are safe and effective for their intended uses when this has not been established (Section 502(a) of the Act).

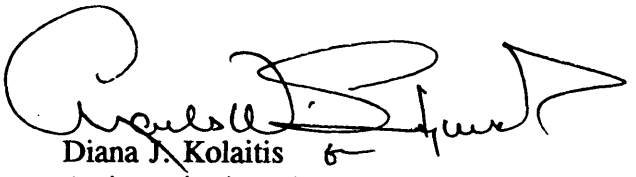
This letter is not intended to be an all-inclusive review of all labeling and products that your firm markets. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations. (This includes all labeling and promotional materials).

We request that you take prompt action to correct these violations. Failure to promptly correction violations may result in enforcement action being initiated by the Food and Drug Administration without further notice. The Federal Food, Drug and Cosmetic Act provides for the seizure of illegal products and for injunction against the manufacturer and/or distributor of illegal products.

Please notify this office in writing within fifteen (15) working days of receipt of this letter as to the specific steps you have taken to correct the stated violations. Your should also include an explanation of each step being taken to identify and make corrections to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, please state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to Lawrence E. Boyd, Compliance Officer, Food and Drug Administration, 1141 Central Parkway, Cincinnati, OH 45202-1097.

Sincerely,



Diana J. Kolaitis
Acting District Director
Cincinnati District